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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,833	11/20/2002	Anil B. Mukherjee	4239-61375	8664

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/019,833	MUKHERJEE ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38 and 47* is/are pending in the application.

4a) Of the above claim(s) *9-17 and 24-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,18-23 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/01, 11/03/04*. 9/20/05 + 10/24/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-38 and 47 are pending.

2. Applicants' Response to Restriction filed on 9/27/06 is acknowledged.

Applicants' election with traverse of Group I, claims 1-8, 18-23, 36-38 and 47 drawn to a method of preventing or treating IgA mediated autoimmune disorders with the elected species of IgA nephropathy is acknowledged.

Applicants' traversal is based on that the '846 publication teaches the treatment of bronchial asthma, the bronchial asthma is IgE mediated and the groups I-VI are related to have special technical feature.

However, the '846 publication also teaches a method of treating SLE with uteroglobin which the specification of instant application defines on p. 2 defines IgA mediated autoimmune disorders.

As referred in the original restriction, Applicant's inventions do not contribute a special technical feature when viewed over the prior art, or meet key critical elements, they do not have a single general inventive concept and so lack unity of invention. The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 9-17, 24-38 are withdrawn from the further consideration by examiner 37 CFR.1.142 (b) as being drawn to a non-elected invention/species.

Claims 1-8, 18-23 and 47 drawn to a method of preventing or treating IgA mediated autoimmune disorders with the elected species of IgA nephropathy are under consideration in the instant application.

3. Applicants' claim for domestic priority under 35. U.S.C. 119(e) is acknowledged.

4. Applicants' IDS filed on 10/18/01, 11/13/04, 9/20/05 and 10/24/05 are acknowledged.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8, 18-23 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an a method of treating IgA mediated nephropathy, SLE with an agent comprising a human uteroglobin as set forth in SEQ ID NO:1, does not reasonably provide enablement for a method of treating or preventing any IgA mediated autoimmune disorders by providing uteroglobin, or fragment, derivative, mimetic or other variant thereof; variant comprises polypeptide having at least 85% homology to uterglobin, or at least 95% homology to uteroglobin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

It is noted on p.25, (Example 6) of the instant specification shows that the prevention of IgA nephropathy has been measured by the fluorescent signal of FITC-IgA. However, it is not clear how the fluorescent signal of IgA in the UG knock-out mice is relevant to mean as prevention of binding of UG to fibronectin. The instant specification p. 2 discloses that the treatment of IgA nephropathy inhibits IgA-fibronectin complex because uteroglobin binds to fibronectin.

Further, Laville et al. (Nephrol Dial Transplant 2004, 19:1947-1951) teach the prevention of IgA nephropathy is uncertain and involve many risk factors to be considered (p. 1947-1948, in particular).

Treatment of IgA nephropathy is achieved by steroid, immunosuppressive drugs or to "symptomatic" treatment approach with ACE inhibitors and/or angiotensin receptor (p. 1948, in particular).

In addition, Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495 in particular, of record).

The art acknowledges that function cannot be predicted based solely on structural similarity to a protein and recognized that it was unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences. Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Thus it is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since the amino acid sequence of a polypeptide determines its structural property, predictability of which amino acid fragment can retain the functional capabilities of the fragment, derivative, mimetic or other variant thereof; variant comprises polypeptide having at least 85% homology to uterglobin, or at least 95% homology to uteroglobin, and guidance with regard to, which segments in the polypeptide's sequence contribute to its function. The specification only provides guidance of a polypeptide consisting of an uteroglobin defined by the SEQ ID NO:1.

Therefore, there is insufficient direction as to how to make and to use a composition comprising any fragment, derivative, mimetic or other variant thereof; variant comprises polypeptide having at least 85% homology to uterglobin, or at least 95% homology to uteroglobin, which can be used as to whether such a desired effect can be achieved or predicted, as encompassed by the claims.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed uteroglobin formulation in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. Claims 1-8, 18-23 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of uteroglobin composition comprising SEQ ID NOL1 but applicant is not in possession of an uteroglobin composition comprising a fragment, derivative, mimetic or other variant thereof; variant comprises polypeptide having at least 85% homology to uterglobin, or at least 95% homology to uteroglobin.

There is insufficient written description encompassing a fragment, derivative, mimetic or other variant thereof; variant comprises polypeptide having at least 85% homology to uterglobin, or at least 95% homology to uteroglobin are not set forth in the specification as filed. Claims 1-8, 18-23 and 47 read on any portion of uteroglobin, and mimetics include any small molecules increase stability of soluble but Applicant fails to disclose even a single species within the genus claimed. Therefore, Applicant does not

possess of scope of claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-8, 18-23 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/53846 as is evidenced by specification disclosure on p. 2-3.

The '846 publication teaches that the method of treating IgA mediated autoimmune disorders including SLE, diabetic nephropathy, glomerulosclerosis, idiopathic nephropathy using human uteroglobin as in SEQ ID NO:1 of claimed (p. 18, claims 23-39 in particular).

The '846 publication further teaches that the human uteroglobin is about 95% pure (claims 9-10, in particular), the routes of administration includes ophthalmic, intravenous, systemic or oral (claims 21-23, in particular) and in combination with corticosteroid (claim 67, in particular).

As a patient is diagnosed with the above mentioned diseases, "identifying a subject..." before administering uteroglobin is inherently achieved. As is evidenced by the p. 2-3 of the instant application, the SLE and glomerulosclerosis are IgA mediated disorders. Thus, the reference teachings anticipate the claimed invention.

9. Claims 1-8, 18-23 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by the U.S. Pat. No. 6,255,281 B1 as is evidenced by the specification disclosure on p. 2-3.

The '281 patent teaches that the method of treating IgA mediated autoimmune disorders glomerulosclerosis, Fn-deposit glomerulonephritis, glomerulopathies and nephropathy using human uteroglobin as in SEQ ID NO:1 of claimed (col. 1, lines 33-41, col. 9, lines 36-44, Exmple 11, in particular).

The '281 patent further teaches that the human uteroglobin is about 99% pure (c col. 10, lines 65-68, in particular), the routes of administration intravenous, systemic or oral (Example 11, in particular) and in combination with corticosteroid (Example 2, in particular).

As a patient is diagnosed with the above mentioned diseases, "identifying a subject..." before administering uteroglobin is inherently achieved.

As is evidenced by the p. 2 of the instant application, the glomerulonephritis and glomerulopathies are encompassed by the IgA mediated nephropathy. Thus, the reference teachings anticipate the claimed invention.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 15, 2006

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